Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Orthomerica Products Inc.	6333 North Orange Blossom Trail Orlando, FL 32810 USA	US-MF-000009882

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
Newport III Orthosis	3640, 3641, 6342, 6343, 3645, 3646, 3647, 3648, 3640.40, 3641.41, 3642.42, 3643.43
Intended Purpose	**Basic UDI-DI**
Post-operative hip revision patients Primary arthroplasty patients at risk to dislocate Patients needing stability after dislocation Inoperable patients requiring hip stabilization Patients who can benefit from a hip orthosis to reinforce hip precautions	Being Assigned UDI 00195003004350 - 00195003004381 00195003004411 - 00195003004442 00195003004473 - 00195003004480 00195003004497 - 00195003004503 00195003004367 - 00195003004398 00195003004428 - 00195003004459

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	1	EN ISO 13485:2016 EN ISO 15223-1
Rule:	1	

Orthomerica declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Najiba Katir

TITLE: Regulatory Compliance **SIGNATURE:** Najiba Katir

PLACE: Orlando **DATE:** 14/07/2021

CE